REMARKS

Claims 4-5 and 8-16 are presently pending. Claim 11 has been allowed in a previous office action. Claim 11 has been amended to correct a typographical error. Claims 4, 5, 9, and 16 have also been amended. Claims 17 and 18 have been added. Thus, claims 4-5 and 8-16 remain pending in this application.

Request for Continued Examination

The Applicants are concurrently filing a Request for Continued Examination ("RCE") that accompanies this response.

Claim Rejections - 35 U.S.C. § 103

Claims 4-5, 8-10, and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,828,716 to McEwan et al. ("McEwan") in view of U.S. Patent No. 6,074,883 to Kelly et al. ("Kelly").

Independent Claim 4

Independent claim 4 is directed toward a method of collecting and separating a patient's blood and recovering a platelet-rich concentrate. The method includes collecting a patient's blood using "a needle set comprising a hollow needle coupled with a tubing having a fitting adapted to engage a first port in an elongated container fitted with a movable plunger having a second port therein". The blood is transferred from the needle through the tubing, the fitting, and the first port into the elongated container by moving the plunger away from the first port. The blood is centrifuged and separated into platelet-rich plasma and red blood cells, which are displaced by moving the plunger towards the first port and expelling the red blood cells into a waste bag through tubing attached to the first port. Platelet-poor plasma is separated by moving the plunger toward the first port and expelling the platelet-poor plasma through the third port of a plunger rod.

The Applicants respectfully submit that a *prima facie* case of obviousness has not been established because the cited references, either alone or in combination, do not disclose, teach, or suggest, several elements of claim 4.

A. McEwan and Kelly Lack "a needle set comprising a hollow needle coupled with a tubing having a fitting", as Required by the Method of Claim 4

Neither McEwan nor Kelly discloses, teaches, or suggests a "needle set comprising a hollow needle coupled with a tubing having a fitting adapted to engage a first port in an elongated container", as recited in claim 4. The Office Action relies upon McEwan in finding that this element is obvious. The needle 36 of McEwan, however, does not include "a **fitting** adapted to engage a first port in an elongated container". Rather, the needle 36 of McEwan is inserted directly into a cap assembly of a blood sample collection chamber. McEwan, FIG. 1b; col. 8, ll. 12-15. Thus, the needle of McEwan would have no use for tubing or a fitting. Likewise, while the Office Action does not rely upon Kelly in alleging that this element is obvious, no such needle set is disclosed in Kelly.

These reasons alone render claim 4 allowable.

B. McEwan and Kelly Lack "a movable plunger having a second port therein"

Furthermore, the cited references do not disclose an elongated container having **a first port** and having a **movable plunger** including **a second port**.

The assembly of McEwan, which the Office Action at page 3 concedes lacks a movable plunger, includes only a single port 32, as shown in FIGs. 1a-1g. A second port as defined in the claims is not disclosed, taught, or suggested in McEwan.

The Office Action suggests that Kelly discloses a movable plunger having a second port. Office Action, p. 3. The Advisory Action states that "Kelly teaches plunger (118) that performs the substantially identical function of the claimed plunger." Advisory Action, p. 2. The Applicants respectfully assert that the end 118 of the capillary tube 114 of Kelly does not perform the substantially identical function of the plunger of claim 4. The carrier tube 102 of Kelly is merely a cylindrical tube (as best shown in FIGs. 1 and 5-6) adapted to attach to the bottom plug 110 and the top collar 112 and adapted to house the capillary tube 114. The operation of the carrier tube 102 is described only with reference to the cap 104 of the carrier tube 102 moving into the capillary tube 114 to create a seal to prevent blood or air to flow out. Kelly, col. 8, l. 36 - col. 9, l. 66.

Nowhere does Kelly disclose using the carrier tube 102 or the end 118 of the capillary tube 114 as a plunger or even that the carrier tube 102 or end 118 is movable. Accordingly, Kelly does not disclose nor suggest using the carrier tube 102 or the end 118 to remove separated components two separate times to remove red blood cells and platelet-poor plasma after two separate centrifuge

processes as required by claim 4. Further, in view of the fact that Kelly only discloses analyzing separated components **remaining within** the capillary tube 114 via an optical reading device (*id.*, col. 6, ll. 10-15; col. 10, ll. 32-43), it seems unlikely – if not impossible – that the carrier tube 102 would be capable of being used as a plunger for removing separated components of the blood from the capillary tube 114. Finally, Kelly's carrier tube 102 does not have a port associated therewith, as does the movable plunger of claim 4.

For these reasons, the Applicants respectfully assert that nowhere does Kelly disclose, teach, or suggest using the carrier tube 102 or end 118 as a plunger "for removing separated components," as stated by page 3 of the Office Action. If this allegation is to be maintained, the Applicants respectfully request that any subsequent office action identify where Kelly states or suggests that the carrier tube 102 or the end 118 of the capillary tube 114 may function as a plunger or be used to remove separated components.

The Applicants submit that McEwan and Kelly lacking this element is yet another reason why claim 4 is allowable.

C. McEwan and Kelly Do Not Disclose "transferring said blood from the needle through the tubing, the fitting, and said first port into said elongated container by moving the plunger away from the first port"

The applied references do not disclose transferring blood from a needle, through a tubing and a fitting coupled to the needle, and into a container that is to be centrifuged. Rather, in McEwan, blood is drawn in a first direction through the needle 36, presumably into a container attached to the needle 36. The blood is then released out of the container in a second, opposite direction back through the needle 36 into the blood sample collection chamber 24. The present invention, on the other hand, does not require a second container for storing the blood before it is transferred into the elongated container because "blood may be introduced directly into container 10 through valve 14" (e.g., the first port). Present Spec., p. 6, ll. 21-22. Furthermore, in the present invention, blood is transferred in a single direction from a patient through the needle, the tubing, the fitting, the first port, and finally, into the elongated container.

Moreover, the applied references do not disclose moving a plunger fitted within the container away from the first port (through which blood enters the container) to transfer blood into the container. As described above, in McEwan, blood is transferred into the chamber by inserting a

needle directly through the cap assembly. It would be virtually impossible for blood to be transferred through the cap assembly of McEwan by moving a plunger away from the cap assembly. Thus, this element is also not disclosed by McEwan.

Although the Office Action does not rely upon Kelly in alleging that the needle set of claim 4 is obvious, this element is also not disclosed in Kelly.

Thus, the Applicants respectfully disagree with the Advisory Action's statement that "the cap assembly performs the identical function of a needle fitting". Advisory Action, p. 2. For these reasons alone, claim 4 should be allowable.

D. McEwan and Kelly Lack the Acts of "moving said plunger towards said first port and expelling said red blood cells into a waste bag"

In addition, the non-cellular component in McEwan is not displaced "**by moving said plunger** towards said first port and expelling said red blood cells into **a waste bag**," as recited in claim 4. In claim 4, the plunger is moved in one direction (away from the first port) to transfer the blood into the container and is moved in an opposite direction (toward the first port) to expel red blood cells. Even assuming, *arguendo*, that the Office Action's statement that "it would have been an obvious step . . . to choose to decant separated blood cells into a bag" were true, the methods of doing so – by moving a plunger toward a first port – would not be obvious. This claim element is likewise not disclosed, taught, or suggested by Kelly.

This is a further independent basis for the allowability of claim 4.

E. McEwan and Kelly Lack the Second Centrifuging Act of Claim 4

Additionally, the cited references do not disclose a second centrifuging act wherein platelet-rich concentrate is separated from platelet-poor concentrate, as in claim 4. The Office Action relies upon column 14, lines 43-51 of McEwan in stating that "McEwan also teaches that the components may be further separated by centrifugation until desired separation is achieved." Office Action, p. 3. This cited portion of McEwan, however, only refers to separation of the "lower density component" from the "denser cellular component." McEwan, col. 14, ll. 46-49. The lighter, low density, non-cellular component is defined by McEwan as serum or plasma while the denser cellular component contains blood cells. *Id.*, col. 11, ll. 25-30. In other words, this statement in McEwan simply refers to separating platelet-rich plasma from red blood cells. Thus, McEwan does **not**

disclose "centrifuging said platelet-rich plasma remaining in said container and separating a platelet-rich concentrate from a platelet-poor plasma", as recited in claim 4. Furthermore, the combination of Kelly and McEwan would only separate the blood into serum and cellular material and therefore not anticipate the separation of platelet concentrate from the serum or plasma, as in claim 4.

F. McEwan and Kelly Lack the Act of "attaching a hollow plunger rod having a third port therein to said plunger and displacing the platelet-poor plasma"

The cited references do not disclose "attaching a hollow plunger rod having a third port therein to said plunger and displacing the platelet-poor plasma" by expelling the platelet-poor plasma "through the third port" of the plunger rod, as recited by claim 4. The Office Action analogizes the end 118 of the capillary tube 114 of Kelly to the hollow plunger rod of claim 4. However, the capillary tube 114 of Kelly does not include a third port, through which platelet-poor plasma is expelled into a waste bag. Thus, this element is also not disclosed by McEwan, Kelly, or a combination thereof.

In finding the argument that a third port is not disclosed by the applied references unpersuasive, the Advisory Action cites *St. Regis Paper Co. v. Bemis Co.*, 193 U.S.P.Q. 8 (7th Cir. 1977). The court in *St. Regis Paper* held that redundancy of layers to confer strength was obvious in the paper bag art. *Id.* at 11. In the present invention, however, the ports are not redundant because each has a distinct purpose. Thus, *St. Regis Paper* does not apply, and a plunger rod having a third port through which platelet-poor plasma is expelled into a waste bag is not obvious over the cited references.

This is yet another reason that claim 4 is allowable.

For at least these **six** reasons, independent claim 4 is allowable over Kelly and McEwan. Claims 8, 10, 12, and 17, which depend from claim 4, are allowable for at least the same reasons.

Independent Claim 5

Independent claim 5 is directed toward a method of collecting and separating a patient's blood and recovering a platelet-rich concentrate. The method includes collecting the patient's blood using a needle set comprising a hollow needle having attached tubing and a fitting adapted to engage a first port in an elongated container fitted with a movable plunger having a second port

therein. A valve positioned within the first port is opened, and the blood is transferred through the first port into the elongated container by moving the plunger away from the first port. The valve is closed, and the blood is centrifuged and separated into platelet-rich plasma and red blood cells, which are displaced by moving the plunger towards the first port and expelling the red blood cells into a waste bag through tubing attached to the first port. Platelet-poor plasma is separated by moving the plunger toward the first port and expelling the platelet-poor plasma through the third port of a plunger rod.

Claim 5 includes many of the claim elements of claim 4 discussed above, including the following:

- a needle set comprising a hollow needle and a fitting adapted to engage a first port;
- "a movable plunger having a second port therein";
- transferring the blood through the first port into the elongated container "by moving the plunger away from the first port";
- "displacing the red blood cells . . . from said container by moving said plunger towards said first port and expelling said red cells through said first port";
- displacing the platelet-poor plasma . . . from said container by moving said plunger towards said first port and expelling said platelet-poor plasma through said second port of said plunger and said third port of said plunger rod".

Thus, claim 5 is allowable for at least the reasons discussed above with respect to claim 4.

Furthermore, claim 5 recites "opening a valve positioned within the first port" prior to transferring the blood into the container and "closing the valve" prior to centrifuging the blood. Neither McEwan nor Kelly discloses, teaches, or suggests these elements.

The Applicants respectfully submit that claim 5 and its dependent claims 9 and 13-15 are allowable for at least these reasons.

Independent Claim 16

Independent claim 16 is directed toward a method of collecting and separating a patient's blood and recovering a platelet-rich concentrate. The method includes collecting blood using "a needle set comprising a hollow needle and a fitting adapted to engage a first port in a container fitted with a movable plunger having a second port therein." The blood is transferred through the

first port into the container by moving the plunger away from the first port. The blood is centrifuged and separated into platelet-rich plasma and red blood cells, which are displaced by moving the plunger towards the first port and expelling the red blood cells through the first port. The platelet-rich plasma is centrifuged to separate a platelet-rich concentrate from a platelet-poor plasma. A hollow plunger rod having a third port therein is attached to the plunger to displace the platelet-poor plasma from the container "by moving said plunger towards said first port and expelling said platelet-poor plasma through said second port of said plunger and said third port of said plunger rod".

Claim 16 includes many of the claim elements of claims 4 and 5 discussed above, including the following:

- "a needle set comprising a hollow needle and a fitting adapted to engage a first port";
- "a movable plunger having a second port therein";
- transferring said blood through said first port into said container "by moving the plunger away from the first port";
- "displacing the red blood cells from said container by moving said plunger towards said first port and expelling said red cells through said first port";
- A second centrifuging act for "separating a platelet-rich concentrate from a platelet-poor plasma"; and
- "displacing the platelet-poor plasma from said container by moving said plunger towards said first port and expelling said platelet-poor plasma through . . . said third port of said plunger rod".

The Applicants respectfully submit that claim 16 is allowable because McEwan and Kelly lack these elements, as provided above with respect to claims 4 and 5.

Dependent Claims 17 and 18

Dependent claims 17 and 18, which depend, respectively, from claims 4 and 16, recite that "the first port includes a valve, the method further comprising opening the valve prior to the act of transferring the blood." As discussed above with respect to claim 5, this element is not disclosed in the applied references.

Thus, for these reasons as well as for the reasons provided above with respect to claims 4 and 16 from which claims 17 and 18 respectively depend, claims 17 and 18 are believed to be allowable over the applied references.

Conclusion

It is the Applicants' belief that all of the claims are now in condition for allowance and action towards that effect is respectfully requested. The Applicants respectfully request that a timely Notice of Allowance be issued in this case. If there are any matters which may be resolved or clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney at the number indicated.

A check covering the fee for a one-month extension of time and the fee for the RCE is enclosed. The Commissioner is authorized to deduct any other fee that may be required (except for payment of the issue fee) to Nixon Peabody, LLP, Deposit Account No. 50-4181, Order No. 247168-000158USD1. A duplicate copy of this paper is enclosed.

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Respectfully submitted,

By _____

Daniel J. Burnham
Registration No.: 39,618
Nixon Peabody, LLP
161 N. Clark St., 48th Floor
Chicago, Illinois 60601
(312) 425-3900
Attorneys For Applicant